There is evidence from one RCT that an energy conservation course run by an occupational therapist decreased the impact of fatigue by 7% in persons with multiple sclerosis

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Clinical Scenario: Fatigue is reportedly one of the most common problems amongst persons with multiple sclerosis (MS). Research has shown that MS related fatigue can have a negative impact on an individual’s ability to engage in their desired occupational performance roles. Energy conservation is a non-pharmacological intervention commonly used by occupational therapists which aims to educate persons on how they can manage their fatigue effectively. Energy conservation strategies are a well established practice but there is no scientific evidence to support their effectiveness. So how effective is energy conservation in decreasing fatigue levels in persons with MS?

Focussed Clinical Question: Is energy conservation effective in decreasing fatigue impact in persons with multiple sclerosis?

SUMMARY of Search, ‘Best’ Evidence’ appraised, and Key Findings:

- Four citations were located that met the inclusion/exclusion criteria
- One systematic review and one randomised controlled trial (RCT) were reviewed to determine trial quality.
- The RCT by Mathiowetz, Finlayson, Matsuka, Chen and Luo (2005) was deemed the “best” evidence and was appraised.
- The RCT measured several outcomes, however, this CAT focuses only on the impact of energy conservation on fatigue levels.
- The RCT reported that the EC course had a significant effect on reducing fatigue as measured by the physical and social subscales of the Fatigue Impact Scale (FIS) compared to persons who did not take the course.
- Interpretation of data showed that after six weeks, the intervention produced a mean between-group difference of 14.1 points on the 200-point FIS scale (95% CI, 5.7 to 25.2). This mean between-group difference equates to approximately a 7% reduction in fatigue impact. While statistically significant, the effect was small (less than 10%).

Clinical Bottom Line: An energy conservation course run for six weeks by occupational therapists resulted in a statistically significant reduction in fatigue, in persons with multiple sclerosis: 14.1 points on a 200-point scale (95% CI, 5.7 to 25.2).

Limitations of this CAT: This critically appraised paper has been individually prepared as a part of a university subject, reviewed and marked by a lecturer, but has not been externally peer-reviewed.
SEARCH STRATEGY:

Terms used to guide Search Strategy:

- **Patient/Client Group**: Multiple Sclerosis, MS
- **Intervention**: Energy conservation, energy conservation education
- **Comparison**: Nil
- **Outcome(s)**: Decreased fatigue levels, fatigue impact

<table>
<thead>
<tr>
<th>Databases sites searched</th>
<th>Search Terms</th>
<th>Limits used</th>
</tr>
</thead>
<tbody>
<tr>
<td>- New Zealand Guidelines group - NHMRC - UK guidelines</td>
<td>Multiple sclerosis OR MS AND energy conservation AND fatigue</td>
<td>Nil</td>
</tr>
<tr>
<td>- Cochrane Library</td>
<td>Multiple sclerosis AND energy conservation AND fatigue</td>
<td></td>
</tr>
<tr>
<td>- Joanna Briggs Institute</td>
<td>Energy conservation, multiple sclerosis, MS</td>
<td></td>
</tr>
<tr>
<td>- PEDro - (The Physiotherapy Evidence Database) - OTseeker - (Occupational Therapy Systematic Evaluation of Evidence)</td>
<td>Energy conservation, multiple sclerosis, MS</td>
<td>2002-present</td>
</tr>
<tr>
<td>- Centre for Clinical Effectiveness</td>
<td>Energy conservation, energy conservation education, multiple sclerosis, MS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Multiple sclerosis AND energy conservation OR energy conservation education AND fatigue</td>
<td>2002-present, Humans</td>
</tr>
</tbody>
</table>

**INCLUSION and EXCLUSION CRITERIA**

**Inclusion Criteria:**
- Studies published in English
- Studies that investigated energy conservation as an intervention for persons with multiple sclerosis
- Studies with fatigue impact as an outcome measure

**Exclusion Criteria:**
- Studies which did not investigate the intervention
- Studies that investigated energy conservation and other diagnosis
- Studies that did not have fatigue as an outcome measure

**RESULTS OF SEARCH**

Four relevant studies were located and categorised as shown in Table 1 (based on Levels of Evidence, Centre for Evidence Based Medicine, 1998)
Table 1: Summary of Study Designs of Articles retrieved

<table>
<thead>
<tr>
<th>Study Design/ Methodology of Articles Retrieved</th>
<th>Level</th>
<th>Number Located</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematic reviews or meta-analysis of randomised controlled trials</td>
<td>1a</td>
<td>n =0</td>
<td></td>
</tr>
<tr>
<td>Systematic reviews or meta-analyses of randomised and non-randomised controlled trial -</td>
<td>2a</td>
<td>n =1</td>
<td>* Steultjens, Bouter, Carolol, Van de Nea, &amp; Vam den Ende (2003). Citation appeared in Cochrane Library, OTseeker, PEDro, PubMed, MEDLINE, Cinahl</td>
</tr>
<tr>
<td>Randomised controlled trials -</td>
<td>1b</td>
<td>n =2</td>
<td>*Mathiowetz, Finlayson, Matsuka, Chen&amp; Luo (2005) Citation appeared in OTseeker, Pubmed, MEDLINE, Cinahl</td>
</tr>
<tr>
<td>Individual cohort studies</td>
<td>2b</td>
<td>n = 0</td>
<td>*Vanage, Gilbertson &amp; Mathiowetz. (2003). n = 9 Citation appeared in PubMed, MEDLINE, Cinahl</td>
</tr>
<tr>
<td>Case control studies</td>
<td>3</td>
<td>n =0</td>
<td></td>
</tr>
<tr>
<td>Case series; post test only, pre test/post test</td>
<td>4</td>
<td>n = 1</td>
<td>* Finlayson (2005).</td>
</tr>
</tbody>
</table>

BEST EVIDENCE

The randomised controlled trial by Mathiowetz, Finlayson, Matsuka, Chen and Luo (2005) was identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting this study were:

- Although systematic reviews are the highest level of evidence, the systematic review identified only reviewed studies of a low quality (clinical controlled trial and case control study). The RCT was of a higher quality and more recent therefore ‘best’ evidence.
- The study met the inclusion/exclusion criteria
- The study addressed the focussed clinical question.
- One of the studies primary outcome measures is fatigue impact
- The RCT by Mathiowetz et al. (2005) is the most recent study.
**SUMMARY OF BEST EVIDENCE**

Table 2: Description and appraisal of the study by Mathiowetz et al. (2005)

| Aim of the Study: | To assess the short-term efficacy and effectiveness of a 6-week energy conservation (EC) course on fatigue impact, quality of life and self-efficacy for persons with multiple sclerosis (MS). |
| Study Design: | The RCT was completed using a cross over design. The “immediate intervention” group received the six-week EC course starting week 2, one week after the screening session followed by a six week, no intervention period. The “delayed control” group had a six-week no intervention control period before they received the EC course in week eight. The EC course was evaluated in both groups in week 13. |
| Participants: | Participants were recruited by post through mailings to individuals on the mailing lists of the Minnesota and Illinois Chapters of the National MS Society, USA. Interested persons (n=305) contacted project directors and were engaged in a two part screening process. The first part occurred via telephone, where inclusion criteria were assessed. The second part of the screening process occurred in person where the Neuropsychological Screening Battery for Multiple Sclerosis (NSBMS) was administered and exclusion criteria assessed. |
| Inclusion Criteria: | Persons who had diagnosis of MS, was aged 18 or over, reported being functionally literate in English, had Fatigue Severity Scale score of four or greater, lived independently in the community and agreed to attend at least five of the six EC sessions |
| Exclusion criteria: | Persons failed one or more sub tests in NSBMS, or had a moderate or severe cognitive deficit. |

169 participants met the criteria and were randomly allocated (by a coin toss) to either the immediate intervention group (n=78) or the delayed control group (n=91). No mention in the paper of concealed randomisation, however communication with the authors revealed that this did occur.

Baseline data (eg age, gender, FIS baseline scores) were not presented for the two groups, delayed and immediate. Table 2 (p 595) compares two groups at baseline (‘during screening’), but only presents ITT participants (n=169 – all participants) vs Compliers (n=131 – the sub-group of study compliers), and in-text data on page 596 (Results) – baseline use of medication for MS, depression and fatigue = 51% v 49% which were comparable.

There was no blinding of assessors (mainly self-reported measures), therapists or participants.

In the immediate group there were 78 participants, 62 received the allocated intervention with no dropouts at follow up post-course, Week 13. The delayed group had 91 participants, 69 received the allocated intervention with one drop out at follow up post course. Non compliers were participants who participated in less than five of the six EC sessions.
**Intervention Investigated**

Packer et al (1995) developed the six-week, community based EC course for adults experiencing fatigue secondary to chronic illnesses. Twelve certified occupational therapists taught the 20 EC courses. The course consisted of six-weeks of highly structured, two-hour classes as described in detail by Packer et al. (1995). Each course included seven to 10 participants per group and was taught in community settings such as MS chapter offices, churches and public libraries. The course used a range of pedagogical techniques including lectures, discussions, goal setting, practice activities and homework activities to assist participants’ integration of EC principles into everyday tasks.

The sessions addressed rest, positive and effective communication, proper body mechanics, ergonomic principles, environment modification, changing standards, activity analysis and modification and setting priorities.

**Control:** The delayed control group received no intervention during the first 8 weeks of the study. They then completed the EC course whilst the immediate group received no intervention.

**Outcome Measures (Primary and Secondary)**

The primary outcome measures in this study were the Fatigue Impact Scale (FIS) and the SF-36 health survey. The secondary outcome measure was the Self Efficacy for Performing EC Strategies Assessment. The outcome measure that will be used to answer the focused clinical question is the FIS; other measures will not be analysed. The FIS data that will be presented were collected at baseline (Week 1) and post-treatment (Week 7). This is because there was no true control group after Week 7 when the delayed group completed the energy conservation course.

The **Fatigue Impact Scale (FIS)** was used to measure the impact of fatigue on participants’ lives, the factors that affected the perceptions of fatigue impact and how fatigue affected general and mental health. The FIS consists of 40 statements that measure fatigue in three areas: physical (range 10-50), cognitive (range 10-50) and psychosocial (range 20-100). Respondents rated the statements on a Likert scale ranging from 1 (no problem) to 5 (extreme problem). The maximum score on the FIS is 200. The FIS was completed by all participants in Weeks 1, 7 and 13.

All measures were administered by research assistants while the course instructors were not in the room. However, it appears that the assessors were not blinded to group allocation. The responses were entered into a computer database by the research assistants. A second (unnamed) person did random checks of accuracy on data entry. All outcome measures were scored by a computer. Post-course data were collected between May 2002 and June 2003.

**Results:** Data from the study were analysed using Intention to Treat (ITT) Likelihood, Last-observation-carried-forward (LOCF) and compliers only analysis. This CAT only focuses on fatigue impact at baseline and week 7, where there was a control and intervention group. The results displayed in table 3.1 and 3.2 are only for the FIS ITT Likelihood at baseline and week 7. The data was calculated based upon raw data obtained through personal correspondence with the authors of the paper.
Table 3.1 Means, standard deviations (SD) and between-group mean differences on the FIS between baseline (Week 1) and post-intervention (Week 7) ¹

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group (n=78)</th>
<th>Control Group (n=91)</th>
<th>Mean Between-Group Difference and 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (Wk 1)</td>
<td>120.9 (29.7)</td>
<td>122.9 (28.9)</td>
<td></td>
</tr>
<tr>
<td>Post-Intervention (Wk 7)</td>
<td>105.8 (24.9)</td>
<td>119.9 (29.9)</td>
<td>14.1 (95% CI, 5.7 to 25.2)</td>
</tr>
</tbody>
</table>

Table 3.2 Between group mean differences and confidence intervals ITT Likelihood FIS subscales at Week 7, in favour of the immediate intervention group ²

<table>
<thead>
<tr>
<th>Dependent variables</th>
<th>n</th>
<th>Mean Difference</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIS Total (40-200)</td>
<td>169</td>
<td>14.1</td>
<td>5.7 to 25.2</td>
</tr>
<tr>
<td>FIS: Cognitive (10-50)</td>
<td>169</td>
<td>3.7</td>
<td>0.9 to 6.5</td>
</tr>
<tr>
<td>FIS: Physical (10-50)</td>
<td>169</td>
<td>3.6</td>
<td>1.3 to 5.9</td>
</tr>
<tr>
<td>FIS: Social (20-100)</td>
<td>169</td>
<td>6.9</td>
<td>2.5 to 11.3</td>
</tr>
</tbody>
</table>

Results summary: There was a 14.1 point reduction in fatigue levels on the FIS (Total score), in favour of the immediate intervention group [on a 200 point scale] after 6 weeks.

Original Authors’ Conclusions

"This RCT supports the efficacy and effectiveness of the EC course to decrease fatigue impact......Thus, this EC course taught by occupational therapists is a legitimate non pharmacological approach for managing fatigue in persons with MS" (Mathiowetz et al. (2005 p 600).

Critical Appraisal:

Validity: (methodology, rigour, selection, bias)
- Ethical approval and written informed consent reported by the authors
- Participants volunteered to be involved in the study. Although participants were not hand picked by the researchers this method of selection has the potential to be bias in favour of the intervention group as volunteers tend to be more motivated.
- Inclusion/exclusion criteria were used to screen participants. Methods of screening were clearly identified and explained by the authors.
- Power analysis was conducted to estimate the number of person needed to complete the study (n=140) and reported by the authors. Numbers were sufficient.
- Co-intervention bias was addressed with participants providing information on medications and other fatigue management treatments they were receiving in weeks one, seven and thirteen. Analysis found that there was no evidence that medication change had a significant impact on the study.
- Participants were randomly allocated to either immediate intervention group or delayed control group by a randomly ordered sequence earlier determined by a coin toss. Blinding of participants to whether they were in the immediate intervention group or the delayed control group was not mentioned

¹ Raw data provided by author of the original paper were used to calculate scores in table 3.1
² Raw data provided by author of the original paper were used to calculate scores in table 3.2

Efforts were taken to ensure treatment fidelity throughout the study and to reduce potential for intervention variation and bias; all therapists teaching the EC course undertook a training session to ensure the course was taught as described in the manual; trained volunteers evaluated course delivery by rating the instructors; participants were evaluated using three quizzes to determine whether they had learnt the main concepts of the course.

Unblinded assessors: Research assistants administered outcome measures and were ‘considered neutral observers and were unlikely to influence participants completion of the self assessments’ (Mathiowetz et al. 2005, p594). However there is no mention that these people were blinded to group allocation, a potential for bias, since the assistants may have influenced the completion of the assessments.

Training in the administration of assessment tools and outcome measures used not mentioned -this would increase the reliability of the findings.

Baseline data was compared using t statistics for continuous variables such as age and Pearson chi-square statistic for discrete variables such as race. This found no significant differences. However, the characteristics of the intervention and control groups were not specifically identified.

**PEDro Scale (Partitioned) Score** = Internal Validity Score: 5/8 Statistical Reporting Score: 2/2 Total Score: 7/10. **Comments**: Internal Validity • Sample was randomly allocated. • Allocation was concealed* (information provided by personal communication with authors – not reported in paper) • Baseline comparability established. • Subjects, assessors and therapists not blinded to intervention • Drop-outs reported (less than 85%). Non compliers identified. • Intention To Treat analysis used. Statistical Reporting • Clear report of methods of analysis used • Reported between group comparisons: nil statistical difference found between the four groups • Results reported in terms of statistical significance • Conclusion were related to results.

**Results:**

- The results section of the paper provided statistics from the analysis of the combined results at baseline, Weeks 7 and 13. These results were unable to be used for appraisal as we are looking at data from baseline and week seven only.

**RESULTS - Wk 1 to Wk 7**

- The results presented in Table 3.2 show that mean differences between groups over six weeks on the FIS were statistically significant (that is, they didn’t occur due to chance). They show a decrease in fatigue impact in favour of the intervention group by 14.1 points (95% CI, 5.7 to 25.2) on a 200-point scale, in persons with MS over six weeks.

  - **This 14.1 point reduction on the 200-point FIS scale equals a 7% treatment effect.**

  - Clinicians cannot be certain that most people with MS would attain an outcome close to the 14.1 point mean difference/decrease in fatigue impact, on the FIS (ie clients could have very good outcomes with up to a 25.2 point decrease in fatigue impact or as little as a 5.7 point decrease). Clinicians may deem this minimum outcome (5.7) to be too small to justify the time and resources involved.

  - The effect of the EC course on fatigue was also statistically significant (in table 3.2) when each subscale (cognitive, physical, social) of the FIS was analysed individually. Fatigue impact was reduced (between-group mean differences) after six weeks by:

    - **3.7 points** on the 50 point FIS cognitive subscale (95% CI 0.9 to 6.5);
    - **3.6 points** on the 50 point FIS physical subscale (95% CI 1.3 to 5.9) and
    - The 3.6 and 3.7 point reductions on the 50-point scale equal a 7% change.
    - **6.9 points** on the 100 point FIS social subscale (95% CI 2.5 to 11.3).

    - The 6.9 point reduction on a 100-point scale also equals a 7% change.
After six weeks, the gains made by the experimental group were small and in the correct direction (i.e. in favour of the treatment group) but would not be considered clinically important (i.e. less than 10% change compared to control group).

The above results differ from the original conclusion in the study. This is because the authors analysed the data from baseline to Week 13, whereas here the data was analysed from baseline to Week 7 where there was a control group.

RESULTS Wk 1 to Wk 13

After 13 weeks, the magnitude of change was approximately the same as at six weeks. Based on data in Table 3 (middle column), p. 597, fatigue impact was reduced (between-group differences) after 12 weeks by:

- **2.89 points** on the FIS physical subscale (95% CI, 0.84 to 4.94) = 6% change
- **4.74 points** on the FIS social subscale (95% CI, 1.16 to 8.32) = 5% change
- **1.98 points** on the FIS cognitive subscale (95% CI, -3.98 to + 0.02): CI crosses zero, indicating that mean differences were not statistically significant.

No information on cost or cost effectiveness of the EC course was provided.

The results cannot be generalised to persons with a moderate or severe cognitive deficit as they were excluded from the study. The results from the study are only generalisable to persons with MS who have similar characteristics of those who took part in the study. This limits the applicability of the findings.

IMPLICATIONS FOR PRACTICE

An energy conservation course run for two hours per week, over six weeks by occupational therapists was effective in decreasing the impact of fatigue in persons with MS by approximately 7%.

This effect of the EC course on fatigue (less than 10%) is not considered clinically significant therefore the implementation of such a course in practice, and the associated time and resources may not be considered worthwhile. However, education on energy conservation should be considered as an intervention, as the course did have a small but positive effect on fatigue in persons with MS.

This intervention and findings are consistent with those described in other studies including Vanage et al (2003) and Mathiowetz et al (2001).

The Fatigue Impact Scale was able to measure changes in fatigue impact across three subscales; physical, social and cognitive. The use of this tool in practice may be beneficial as an outcome measure when working with persons with MS.

EDUCATION

At university in Australia, occupational therapy students are not taught a great deal about energy conservation as an intervention. It is recommended that students be taught about, and practice application of energy management with a variety of diagnoses. Also students would benefit from being exposed to, and practice using outcome measures such as the FIS.

FUTURE RESEARCH:

- Future studies should explore alternative formats of the course (e.g. in Australia) in order to determine the efficacy of energy conservation in multiple settings such as inpatient rehabilitation settings, community health centres etc.
- The investigation of self-learning modules may also be beneficial as such modules may enable persons who live in rural or remote areas to learn the course content on their own or in a group format via distance education.
- An EC course is only one method of fatigue management. Alternative methods of energy conservation should also be investigated either alone or in combination with the EC course. For example education could be provided together with exercise to decrease fatigue impact.
- Further research could also investigate which type of persons can benefit from the EC course in its current format and who does not benefit from the course. This would provide insight into whether the EC course should be recommended.

REFERENCES


Article that was critically appraised:


Related Articles (not individually appraised)

Level 2 Evidence:


Level 4 Evidence:


Level 3 or 5 Evidence: Nil